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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,750	10/11/2001	Benjamin Spenser	501015.20501 (24230.53)	9407

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/14/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,750

Applicant(s)

SPENSER ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 13,23,24,27,28,31,32 and 37-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15, 17, 18, 21, 22, 25, 26, and 33-36 is/are rejected.
- 7) ☒ Claim(s) 16, 19, 20, 29 and 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 12, 14. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-36 in Paper No. 15 is acknowledged. The traversal is on the ground(s) that the search is co-extensive and the product claimed could not be used without a balloon catheter. This is not found persuasive because, as described in the last office action, the inventions have acquired a separate status in the art as shown by their different classifications. Furthermore, as presently claimed, the product merely defines a support stent **capable** of being crimped and delivered with a catheter. Therefore the claimed structure of the stented valve could be implanted through open heart surgery without a catheter.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 37-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Furthermore, Examiner has determined that claims 13, 23, 24, 27, 28, 31, and 32 are not readable on the elected groups of species and are therefore withdrawn.

Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Specification

3. The disclosure is objected to because of the following informalities: in lines 5-7 of page 15, "28" is used to described different elements.

Appropriate correction is required.

Claim Objections

4. Claim 19 is objected to because of the following informalities: line 2 of claim 19 should read "made from a coiled polymer, coated by a coating layer of the same polymer".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 29 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 1 of claim 29 recites "the main body" which lacks proper antecedence.

Claim 36 is indefinite because line 12 recites "rigid support beams" which are also defined in line 7. Therefore it is unclear if the second recitation is a new element or further limitation to previously defined element.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claim 1-7, 10, 11, 14, 17, 18, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Schreck US PN 6,454,799.

Schreck discloses in figures 1-3, lines 16-65 of col. 6, and lines 33-63 of col. 7 a tricuspid heart valve comprising annular stent 24, equidistantly spaced rigid support beams 42 with bores 56, 80 for stitching, and leaflets 32 of biological tissue or synthetic polymers (PET).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 8, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Boretos et al. US PN 4,265,694 or Wheatley et al. US PN 6,171,335.

Schreck meets the structural limitations of claims 8, 33, 34, as described above, but lacks the express written disclosure of using polyurethane for the leaflets (claim 8, 33) or for the support beams (claim 34). Both Boretos (see abstract) and Wheatley et

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al. (lines 48-51 of col. 2 and lines 23-29 of col. 3) teach heart valves comprising posts and leaflets made from polyurethane in order to provide a biocompatible implant.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using polyurethane for the leaflets and support beams, as taught by Boretos and Wheatley et al., in order to provide a biocompatible implant .

11. Claims 9,25,26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Bessler et al. US PN 5,855,601.

Schreck meets the structural limitations of claims 9,25,26, as described above, but lacks the express written disclosure of using nickel-titanium for the stent and the particular ranges of diameters. Note lines 3-6 of col. 13 describe a self expanding valve component. Bessler et al. teaches in lines 3-18 of col. 6 a heart valve having a self expanding nickel titanium stent having initial diameter of about 4mm and would be capable of expanding to about 25mm in order to provide a biocompatible means of securement.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using nickel-titanium alloys and the particular diameters for the stent, as taught by Bessler et al., in order to provide a biocompatible means of securement for the heart valve.

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12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Ogle et al. US PN 6,468,660.

13. Schreck meets the structural limitations of claim 12, as described above, but lacks the express written disclosure of using chemical adhesives to attach the support beams. Note lines 66 of col. 6 through line 4 of col. 7 describe the beams as being attached to the stent. Ogle et al. teaches in lines 10-20 of col. 10 a chemical adhesive for heart valve supporting structure in order to securely bond parts during manufacture.

14. Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using chemical adhesives, as taught by Ogle et al., in order to securely bond parts during manufacture.

15. Claims 21,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 as applied to claim 1 above and in further view of Rosen US PN 4,345,340.

Schreck meets the structural limitations of claims 21,22, as described above, but lacks the express written disclosure of employing radiopaque markers on the valve. Note lines 1-3 of col. 13 describe the use of radiopaque markers, but are unclear as to whether the markers are located on the valve or delivery device. Rosen teaches in lines 19-31 of col. 2 the use of radiopaque markers on a heart valve in order to assist implantation.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by including radiopaque markers, as taught by Rosen, in order to assist the implantation procedure.

16. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck US PN 6,454,799 in view of Boretos et al. US PN 4,265,694 or Wheatley et al. US PN 6,171,335. as applied to claim 33 above, and in further view of Ogle et al. US PN 6,468,660.

Schreck in view of Boretos et al. or Wheatley et al. meets the structural limitations of claim 35, as described above, but lacks the express written disclosure of using chemical adhesives to attach the support beams. Note lines 66 of col. 6 through line 4 of col. 7 describe the beams as being attached to the stent. Ogle et al. teaches in lines 10-20 of col. 10 a chemical adhesive for heart valve supporting structure in order to securely bond parts during manufacture.

Therefore it would have been obvious to one of ordinary skill at the time of the invention to modify the valve disclosed by Schreck by using chemical adhesives, as taught by Ogle et al., in order to securely bond parts during manufacture.

Allowable Subject Matter

17. Claims 16, 19, 20, 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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18. Claim 29 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM
January 12, 2004

BRUCE SNOW
PRIMARY EXAMINER